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**Title of Study: IN-HOME-PD: A Novel Model of Care in Advanced Parkinson's Disease**

Protocol Number: 17080209

**Sponsor:** National Institutes of Health (NIH) / National Institute for Neurological Diseases and Stroke (NINDS) K23NS097615

RUSH

# Subject Information Sheet and Consent Form
## *HVP-Patient Subjects*

## Introduction
You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

## Why are you being invited to participate in this study?
You are being asked to take part in this study because you are a patient at the Rush Parkinson's Disease and Movement Disorders Program who has been diagnosed with Parkinson's Disease (PD) and who is eligible to participate in the Home Visit Program (HVP) research study. The information (data) collected from the study participants will be compared to data available in the National Parkinson's Foundation's Parkinson's Outcome Project. The data will be matched according to age, gender, and disease severity.

Your involvement in the study will contribute to scientific knowledge about whether home visits with individuals with PD can improve patient quality of life, decrease the level of caregiver strain, and help reduce the number of emergency room and hospital visits, and admissions to long-term care institutions.

## What is the purpose of this study?

Advanced Parkinson's Disease is a debilitating, costly, and understudied condition. Improving access to comprehensive, specialized, in-home patient care and caregiver support offers the potential to improve patient quality of life of PD symptoms. The purpose of this study is to test whether and to what degree an interdisciplinary home visit program, with and without peer mentoring for caregivers, will improve patient- and caregiver-reported outcomes over the course of one year and reduce healthcare costs when compared with usual care in advanced Parkinson's Disease.

## How many study subjects are expected to take part in the study?

We estimate 65 people will participate in the home visit patient arm, plus a caregiver for each home visit patient, plus 40 caregiver peer mentors for a total of 170 people participating. The three study arms include home visit patient subjects, home visit caregiver subjects, and caregiver peer mentors.

## What will you be asked to do?

If you agree to participate in the study, you will be asked to participate in four study visits, which will involve in-home clinical assessments and completion of some questionnaires. Additional information will be obtained from your routine medical records: your medical and medication history, family history, neurological examination findings, and office visit records.

**Visit 1:**

This visit will be about 3 hours in length. This visit will begin with the completion of this consent form, followed by collection of basic information such as age and education, and a brief medical and social history. Next, a nurse will measure your vital signs, complete a home safety assessment, and medication reconciliation, in which s/he verifies that our records of your medication regimen are correct. A neurologist will be present by telemedicine (videoconferencing) and will perform a neurological examination, much like the examination performed at office visits to your neurologist. The team will also complete a brief exam which assesses your memory and thinking.

Then, a social worker and/or a nurse will administer various questionnaires about your current function and concerns. These may include questions specifically about the effect of Parkinson's disease on your quality of life. The social worker will also have your caregiver complete a psychosocial assessment.

To conclude, you will have an opportunity to discuss any concerns you have about your health or care which have not yet been addressed. The team may suggest referrals which may support or improve your care.

**Visits 2, 3, and 4:**

These follow up visits will be about 2 hours in length each. These visits will include the same components as the first visit except they will not include further collection of basic information and written informed consent completed at the first visit, and they will include brief additional surveys on satisfaction The second and third visit will occur approximately four months apart and sometime between the first and fourth visit; you will have an opportunity to schedule these visits with the HVP research team at your convenience.

During the follow-up visits, you will be asked to complete some questionnaires, some of which will be self-administered and some of which will be administered by a study staff member. For

the second, third, and fourth visits, the social worker may be present in person or by videoconferencing. This means that the study team will visit you at your home and bring an iPad or other technology that allows you to see and talk with the doctor and ask any questions you might have.

Home visits 2- 4 will occur approximately every four months. The fourth visit will be scheduled approximately 1 year (+/- 60 days) from your initial study visit. You will again be asked to complete some of the same assessments that you completed during the first visit, and a new assessment about the HVP.

The activities conducted in each visit—including history, physical, medication evaluation, and needs assessment—are considered routine care. Conducting these activities in your home and with the use of videoconferencing is considered experimental, and some of the questionnaires that you will complete are done strictly for the purposes of research. These will help us understand whether this type of care is beneficial to you and should be studied further.

## How long will you be in the study?

You will be in the study for approximately one year, starting with an initial 3 hour home visit. Three follow-up home visits will take place after the initial visit, occurring approximately every three to four months. You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you or to the study team, you are unable to participate in the study as directed, or the study is canceled.

## What are the possible risks of the study?

There are no known risks from participating in neurological or neuropsychological tests. You may experience mild boredom or cognitive fatigue; however, most individuals find the tests interesting and are able to tolerate 2-3 hours of testing well. You can skip any questions that make you uncomfortable or that may cause you emotional distress.

## Are there benefits to taking part in the study?

The potential benefits to you are as follows: (1) continuity of medical care via in-home visits with clinical specialists from multiple healthcare disciplines ; (2) time and travel costs saved by having the interdisciplinary team come directly to the home rather than traveling to an outpatient clinic; (3) the possible improvement of both motor and non-motor symptoms via treatment recommendations from the MD and RN, as well as the recognition of combined psychological and social needs and provision of related referrals by the SW; (4) the possible diagnosis of poorly controlled motor symptoms of PD, for which the study team would be able to offer treatment recommendations, and (5) the satisfaction of having contributed to knowledge about Parkinson's Disease and other movement disorders that may help to increase the quality of life for you and other patients with movement disorders.

The potential benefits to society include: (1) increasing the independence, quality of life, and productivity of patients with Parkinson's disease and other movement disorders, (2) extending treatment and support into the home, (3) enhancing safety, (4) increasing access to care, (5) reducing hospitalizations and nursing home placements, (6) reducing the strain on caregivers, and (7) decreasing the costs of unnecessary or dangerous healthcare.

## What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- You may choose to continue to seek care for Parkinson's Disease at the Rush Parkinson's Disease and Movement Disorders Program or elsewhere regardless of whether or not you choose to participate in the study.
- As an alternative to entering the study, you may choose to seek care from home care agencies. You are free to discuss alternatives to entering this study with your personal physician.

## What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected. If you participate, you will be assigned a unique identification number. Your name and other identifying information will only be associated with your identification number on a code sheet that will be password-protected and stored separately from all other study documents. The data for the study will be entered into a secured, electronic database that is password protected. Only the study team will have access to the database, which is protected by the Rush University electronic security systems and firewall. All paper copies of documents related to the study will be reviewed for any identifying information, and should such information be detected, it will be removed. All paper copies of documents will contain only your unique identification number.

This study is sponsored by the National Institute for Neurological Diseases and Stroke (NINDS), a branch of the National Institutes of Health (NIH). The NIH may require access to your files as they pertain to this research study as part of routine monitoring or in the event of an audit.

If you withdraw from this study, the data already collected may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.
In order to conduct the study, the study doctor, Dr. Jori Fleisher, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## What are the costs of your participation in this study?

There will be no cost to you associated with participation in this study. The home visits, educational information, and follow-up phone calls are provided free of charge by the study. However, in the course of this study, we may refer you to a medical, therapeutic, and/or social service that we believe would benefit your care. It is your choice whether or not to obtain these services. The cost of these services will not be covered by study. You and/or your health insurance may be billed for the costs of these services as part of your usual medical care. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility. You may choose to decline any referrals at any time, for any reason.

## What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by the National Institutes of Health (NIH) to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs.

## Will you be compensated or paid?

You will not receive any incentives, rewards, or compensation for being in this study.

## What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. NIH has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

## What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible. You will be provided with an Aware in Care kit as part of this study, which you should bring with you to the emergency room or hospital any time you go. The kit contains a wallet card with your identifying information and the contact information for the study doctor.

## Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Jori Fleisher, (312) 563-2900. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

**SIGNATURE BY THE SUBJECT OR THE SUBJECT'S LEGAL REPRESENTATIVE:**

| Name of Subject | Signature of Subject | Date of Signature |
|---|---|---|

| Subject Assent | Date of Signature |
|---|---|

| Legal Representative's Signature | Date of Signature |
|---|---|

**SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:**
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject or the subject's legally authorized representative. I further attest that all questions asked by the subject or the subject's legal representative were answered to the best of my knowledge.

| Signature of Individual Obtaining Consent | Date of Signature |
|---|---|

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

**SIGNATURE OF THE PRINCIPAL INVESTIGATOR**
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

| Signature of the Principal Investigator | Date of Signature |
|---|---|

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.